

C T F A

5644 '00 JUN -2 P2:12 THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

June 2, 2000

E. EDWARD KAVANAUGH
P R E S I D E N T

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Over-the-Counter Drug Products:
Public Hearing; Docket No. 00N-1256

Dear Sir or Madam:

This is to notify you of the intention of The Cosmetic, Toiletry, and Fragrance Association (CTFA) to participate in the public hearing on June 28-29 to discuss the agency's approach to regulating over-the-counter (OTC) drugs. This notice is submitted pursuant to FDA's notice published in the *Federal Register* on April 27, 2000.

CTFA is the national trade association representing the personal care products industry. Founded in 1894, CTFA represents approximately 600 companies. Approximately one-half of those members are manufacturers or distributors of finished personal care products, including products that are regulated both as cosmetics and OTC drugs. The remaining companies in CTFA's membership are suppliers of goods and services to our active members.

CTFA has represented the growing portion of the OTC drug market that consists of products regulated as both cosmetics and OTC drugs before the agency for many years. These products provide public health benefits to consumers in an increasingly broad array of products that are appropriate for everyday use. CTFA's representation of the OTC drug industry has included participation in consideration of monographs affecting sunscreens, topical antimicrobial products, oral care products, antiperspirants, antidandruff shampoos and other product categories. Many of these monographs are still under active consideration by the agency.

In addition, CTFA represents the unique and distinct interests of the cosmetic-drug segment of the OTC drug market on broader issues such as the recent OTC drug labeling regulation. As that proceeding has demonstrated, regulatory solutions that may be feasible for some parts of the OTC drug market are not always appropriate for cosmetic-drugs.

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CTFA requests a total of thirty (30) minutes for presentations by a maximum of two speakers. Our presentation will relate to several issues identified in FDA's *Federal Register* notice of April 27, 2000. The presentations will be made by Thomas J. Donegan, Vice-President-Legal & General Counsel of CTFA, a member of CTFA's staff, and a possible additional, independent speaker who also will address the issues identified below. The identity of the additional speaker will be provided immediately upon confirmation. Under no circumstances will the total presentation exceed 30 minutes.

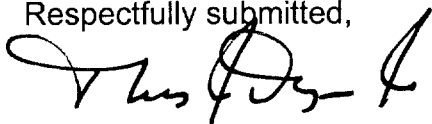
CTFA's presentation will focus on the important public health benefits that are provided to consumers by the availability of drug therapies in traditional drug products and in products that also provide cosmetic benefits. These include products that provide widely-recognized public health benefits such as sunscreens.

We will provide suggestions on how the drug approval process – in particular the OTC Drug Review -- and decision-making regarding general OTC drug labeling issues – could be modified to provide greater flexibility to make cosmetic-drug products available to the consumer without sacrificing the critical elements of safety and efficacy.

In addition, we will discuss the importance of international harmonization of regulations for drugs and cosmetic-drugs. This includes recognition of other systems of regulation throughout the world, and expedited approval of new active ingredients for products that are regulated as drugs in the United States and as cosmetics in other parts of the world.

Thank you for your consideration of this request. If you have any questions or need further information, please feel free to contact me or Elizabeth H. Anderson, CTFA Assistant General Counsel, at (202) 331-1770.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Thomas J. Donegan, Jr.", written in a cursive style.

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel

cc: Patricia L. DeSantis (HFD-2)